

Space-derived Health Aids

Human-implantable devices for improved disease control highlight a sampling of spinoffs in the field of health and medicine

A cardinal rule of spacecraft design is that everything destined for orbit must be superefficient yet as small and as light as technology permits. This is especially true of the family of small satellites, some no larger than a beach ball, intended to meet specific research objectives at minimal cost. In developing these models of compactness, researchers have performed astonishing feats of "microminiaturization," reducing electronic and other components to incredibly tiny dimensions.

A leader in small spacecraft design is the Applied Physics Laboratory (APL) of Johns Hopkins University, Howard County, Maryland. Not coincidentally, APL is also a leader in development of medical systems, particularly devices that can be implanted in the human body. The organization's work in transferring microminiaturization and other space technologies to the field of medicine is one of the outstanding examples of the spinoff process.

The latest of APL's developments, scheduled for first human implant this year, is the Programmable Implantable Medication System (PIMS). Being developed in cooperation with Goddard Space Flight Center (GSFC) and several commercial firms, PIMS is a microminiaturized, computer-directed system for continuous delivery of medication to target organs, in precisely controlled amounts, from a source within the patient's body.



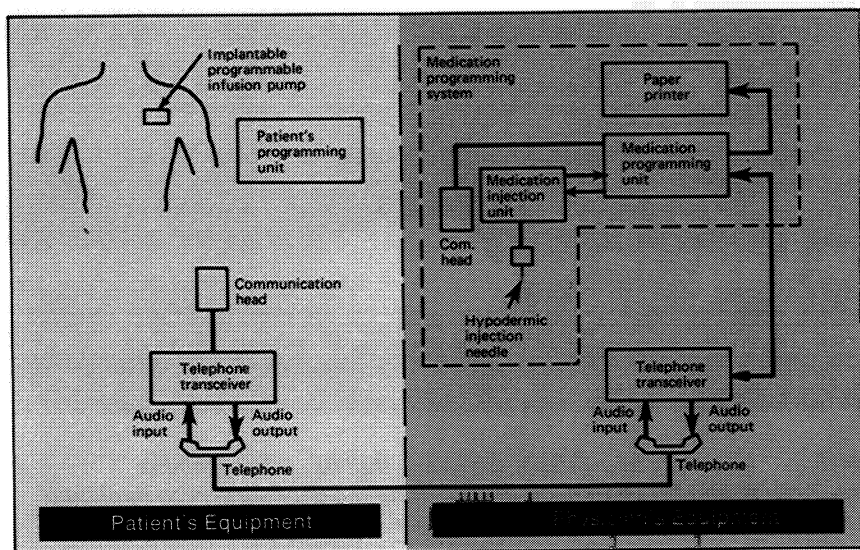
One important application is treatment of diabetes, wherein a malfunctioning pancreas fails to create enough of the hormone insulin to keep the amount of sugar in the blood at a normal level. Many diabetics—more than a million in the United States—need daily or twice daily injections of insulin. PIMS, serving as an electronic artificial pancreas, could free them of this daily ritual and provide further benefit in better control of the body's blood sugar level. Research with external pumps indicates that metering of insulin in tiny amounts over a long period of time is more effective in normalizing many aspects of metabolism than is the injection method. With a pumping system like PIMS, it could be possible to minimize complications

This device is a computerized pumping unit, part of a new Programmable Implantable Medication System for continuous delivery of medication—insulin, for example—from a source within a patient's body. About the size of a woman's compact, it contains a reservoir of medication, a tiny pump, a tube leading to the target area of the body, a battery, and the microminiaturized electronic system shown in the lower view.

of severe diabetes, such as eye, kidney and blood vessel damage caused by fluctuating blood sugar levels.

The key element of PIMS is the Implantable Programmable Infusion Pump (IPIP), contained in a package about the size of a woman's compact and implanted in the shoulder or abdominal area. IPIP consists of a mini-computer that controls the dosage, a reservoir for the medication, a tiny pump, a plastic tube leading from the pump to the target organ, and a lithium battery to power the electronics and pump.

The other major PIMS segment is the Medication Programming System (MPS) in the physician's office. The MPS includes an electronic system for programming IPIP's medication delivery according to the patient's needs. Programming is accomplished by wireless telemetry—a space technology—in which command signals are sent to IPIP by means of a



The diagram shows how a physician can communicate via telephone line with the implanted pump's computer. The computer reports stored information to a receiver in the doctor's office. The physician can reprogram the system—change the dosage—by means of an electronic programmer. Refilling the medication reservoir is accomplished—in the doctor's office—by hypodermic injection.

transmitting antenna called a communication "head." The physician can also "interrogate" the computer; he can, for instance, ask how much medication remains in the reservoir and get a reply in the form of a printed readout.

Since both patient and physician could have communication heads hooked up to a telephone transceiver, visits to the doctor's office would be minimized. The patient places the communication head over the implanted device, presses a button, and the physician is in touch with IPIP's computer. The physician can interrogate the computer and reprogram the medication flow rate after determining how the patient is responding to treatment. In doctor/computer communication, another space technology—called pulse coded modulation—plays a safeguarding role; IPIP will accept only properly coded instructions and will not respond to false signals generated by other sources.

When the computer reports its medication is running low, the patient is summoned to the physician's office for a refill, accomplished by hypodermic injection through IPIP's self-sealing membrane. The reservoir is designed to hold enough medication for long term treatment, the time varying with the application and the dosage. In diabetes treatment, for example, the patient would have about a three-month supply.

A particularly important feature of PIMS is a unit which enables the patient to change his own dosage. Insulin recipients, for example, need more medication after meals. The IPIP is programmed to understand signals describing six types of meals. Holding a small device over the implant, the patient could, for example, dial "medium mixed meal" and the pump would temporarily increase the insulin dose, then resume its normal output.

Although insulin delivery is the most immediate application, PIMS offers similar advantages in treatment of other diseases where long term injection from an internal source seems indicated. Examples include programmed metering of blood-thinning drugs to prevent coronary occlusion or stroke; chemotherapeutic drugs for inoperable tumors; methadone for drug addiction; antabuse for alcoholism; or opiates for pain.

PIMS involves the work of several cooperating organizations in addition to APL. GSFC is providing program management and technical expertise. Pacesetter Systems, Inc., Sylmar, California, a medical equipment manufacturer, is providing part of the funding and will produce the system for the commercial market. Parker-Hannifin Corporation's Biomedical Products Division, Irvine, California is developing the fluid handling system. Novo Research Institute, Copenhagen, Denmark is developing a special, concentrated insulin to reduce the volume needed for long term dosage.

PIMS is one of a number of implantable devices developed by APL, in cooperation with GSFC and other groups, over the past decade. Some of the others are described on the following pages.

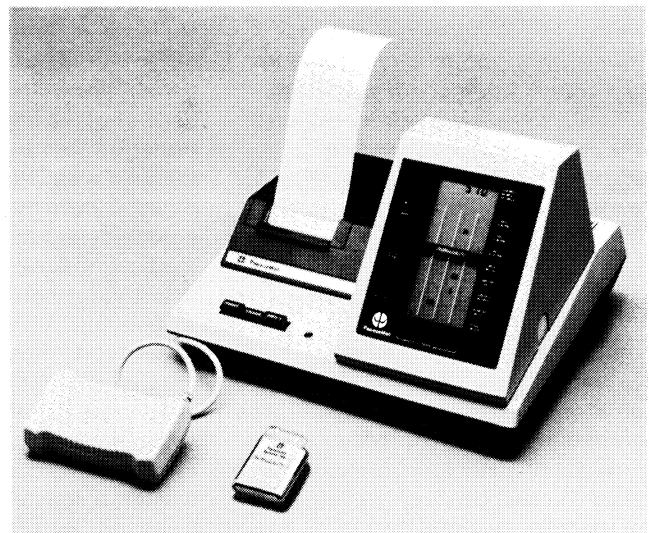


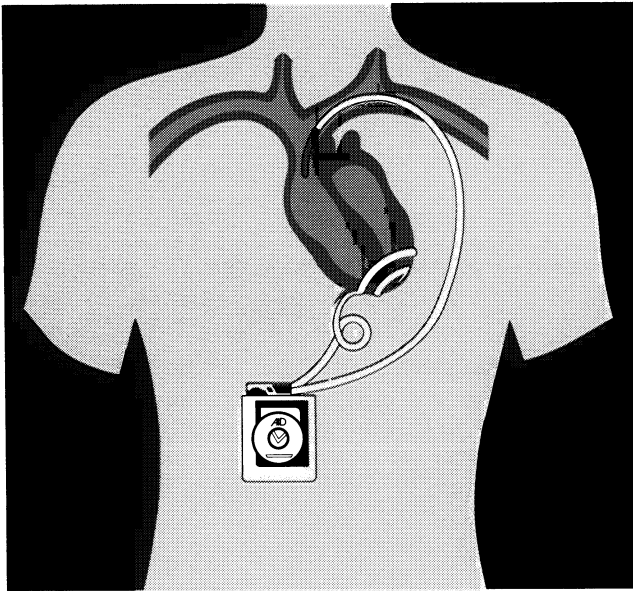
Wearer of a "Pacer"—a rechargeable cardiac pacemaker—the child is shown with the recharging unit. First of a series of implantable systems developed by the Applied Physics Laboratory (APL) of Johns Hopkins University, the Pacer represented a major advance in

heart-assist devices in that its rechargeability eliminated the recurring need for surgery to implant a new battery. Produced by Pacesetter Systems, Inc., the Pacer is based on technology developed for spacecraft electrical power systems.

Pacesetter Systems and APL jointly developed the advanced cardiac pacing system shown, which permits a physician to reprogram a patient's implanted pacemaker without surgery. Called Programalith®, the system consists of the pacemaker (foreground) together with a physician's console containing the programmer and a data printer. The physician communicates with the pacemaker by means of the communicating head (at left), which is held over the patient's chest; signals are transmitted by wireless telemetry. The two-way communications capability allows the physician to interrogate the pacemaker as to the status of the heart, then to "fine tune" the device to best suit the patient's needs, which may change over time with changes in physical condition. Programalith incorporates space technologies used to send coded instructions or queries to satellites and to receive replies from the satellites.

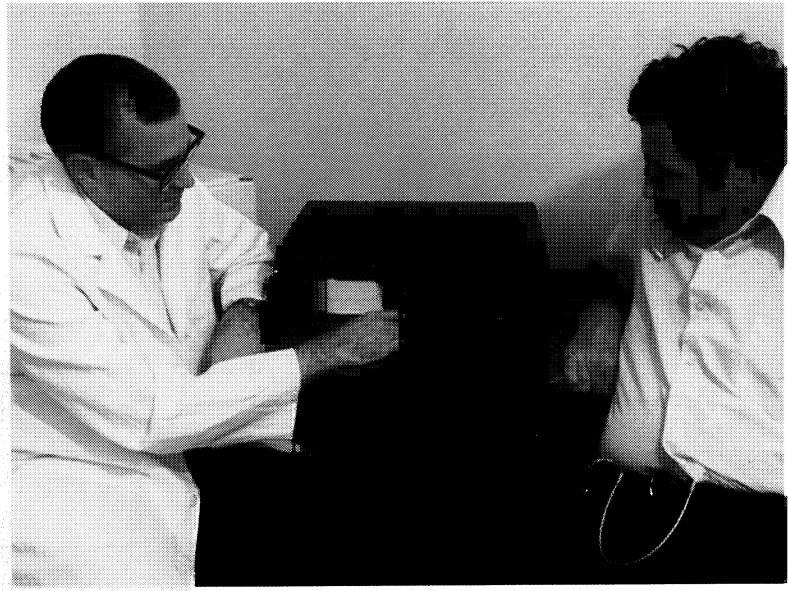
®Programalith is a registered trademark of Pacesetter Systems, Inc.





A spinoff from miniaturized pace circuitry is the new heart-assist device shown above, the AID® implantable automatic pulse generator. Designed to prevent thousands of deaths caused by the erratic heart action known as ventricular fibrillation, the AID pulse generator monitors the heart continuously, recognizes the onset of fibrillation, then administers a corrective electrical shock. Included in the implantable unit are a mini-computer, a power source, and two electrodes which sense heart activity.

Now undergoing clinical test, the AID pulse generator was developed by Medrad Incorporated and Intec Systems, Inc., both of Pittsburgh, Pennsylvania, in conjunction with Drs. M. Mirowski and M. Mower of



Sinai Hospital and Johns Hopkins University Hospital, both of Baltimore, Maryland. With NASA funding, APL conducted an independent evaluation to assure that the system was ready for trials in selected patients who have high risk of experiencing ventricular fibrillation. APL also developed an associated system. Shown at top right, it includes an external recorder to be worn by AID patients and a physician's console to display the data stored by the recorder. This system provides a record of fibrillation occurrence and the ensuing defibrillation, information important to the physician in prescribing further treatment.

®AID is a registered trademark of Medrad Incorporated.

A cooperative development involving NASA, APL, Pacesetter Systems, several medical centers, and industrial participants is the Programmable Rechargeable Neuropacemaker (PRN), an implantable human tissue stimulator designed to provide relief to patients with disorders treatable by electrical stimulation—for example, back, leg and arm pain, cancer pain, and multiple sclerosis. A spinoff from spacecraft electronics technology, PRN allows the physician to adjust stimulation according to the treatment needs of the particular disorder. He does so by means of the command programmer pictured, which sends signals to the implanted device by telemetry.

